REMARKS

The issues outstanding in the advisory action of August 28, 2001, prior to filing of the present request for continuing prosecution, were the objection to claim 22 and the rejections under 35 U.S.C. §§ 102 and 103, as well as the requirement for restriction. It is respectfully submitted that each of these issues should be withdrawn, in view of the following discussion.

Objection To Claims

Claim 22 has been objected to as depending on non-elective claim 3. It is not fully understood why this claim has been singled out for this objection, since various other claims also depend upon non-elected claims. In the event, in view of the discussion concerning the restriction requirement, it is submitted that all of the claims should be examined at this juncture. Withdrawal of the objection is therefore respectfully requested.

Requirement For Restriction

The claims of this application have been segmented into four groups:

Group I, claim(s) 1, 2, 4, 5, 8-25, 39, drawn to a method of qualitative and/or quantitative detection of analytes in liquid/solid phases using ferromagnetic or ferrimagnetic substances as labels;

Group II, claim(s) 3, 6, 7, drawn to a method of quantitative and/or qualitative detection of analytes in immunoassays of other binding assays using magnetic field sensors and external magnetic field;

Group III, claim(s) 26, 36-38, drawn to a method for detection of ferromagnetic substances that are introduced into a human body or applied to a human body; and

Group IV, claim(s) 27-31, 35, drawn to a method for detection of ferromagnetic substances that are introduced into a human body or applied to a human body using external magnetic field and magnetic field sensors.

Groups I and II employ ferromagnetic or ferrimagnetic substances to detect analytes and

those in Groups III and IV use ferrimagnetic or ferromagnetic substances to detect magnetically labeled structure-specific substances in a human. The claims of Groups II and IV further recite that external magnetic fields are employed. It is thus respectfully submitted that all four groups employ the "same or corresponding special technical feature", that is, the use of ferrimagnetic or ferromagnetic substances as labels to detect substances either *in vitro* or *in vivo*. In all four groups of claims the technical features of the invention are essentially the same, that is, materials labeled with magnetic substances are detected through the use of typical magnetization detection techniques. It does not matter whether the sample measured is a human, or an analyte in vitro, nor does it matter whether or not an external magnetic field is used (in fact, the Office Action does not suggest what process other than an external magnetic field could be employed). While the Office Action attempts to define the "special patentable features" as the use of external sensors or the use of detection techniques in human bodies, it can be seen that the same procedure and "special patentable feature" is being applied regardless of on what or where the detection techniques are being used. Thus, it is submitted that, under 37 C.F.R. §1.475, the groups of invention set forth in the Requirement for Restriction do not contain different special patentable features and, therefore, that the Restriction Requirement should be withdrawn.

In conclusion, it is submitted that the "special technical feature", as fully explained below in connection with the rejections over art, clearly is contained in all four of the groups created in the restriction requirement, and thus mandates withdrawal thereof. The same is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 1, 2, 4 and 5 are rejected, under 35 U.S.C. § 102(b) over JP '442(TDK), and claims 22-24 over *Cohen*. Reconsideration of these rejections is respectfully requested.

As acknowledged in the advisory action of August 28, 2001, *TDK* teaches a heterogeneous immunoassay, see pages 4 of the advisory action. As noted in that advisory action, heterogeneous immunoassay is defined as a method in which separation of bound from unbound material is required, as the office action agrees occurs in both *TDK* and *Cohen*. Indeed,

such is the art recognized definition of heterogeneous immunoassay, as evidence by *Chan*, "General Principles of Immunoassay", chapter 1, page 1, 13 and 18 (attached). However, the present invention is directed to a new variant of a homogeneous immunoassay. This assay is based on the measurement of the relaxation behavior of magnetic particle conjugated antigen or antibodies. In this assay discrimination between bound and unbound magnetic particle conjugated antigen or antibodies is possible without any separation and/or washing step due to the mass dependent relaxation behavior of the particles. In contrast, *TDK* discloses another principle, i.e. the agglutionation immunoassay which presumes a precipitation step before the determination of the particle size by remanent magnetic flux density measurement. The *Cohen* patent discloses a common competitive enzyme immunoassay, the assay described by *Cohen* having magnetic separation of bound and antibodies, but still requiring separation.

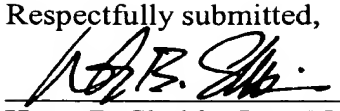
In preparation of the present amendment, it was noted that an incorrect term was used in the independent claims, which inadvertently recited a "heterogenenous" assay, where as, evident from pages 6, the second paragraph, and page 14, the sentence bridging that page through page 15, that a homogeneous immunoassay is described in the present application. As admitted in the office action, heterogeneous assay is taught by the references, it is submitted that the presently claimed process, which avoids the need for separation of unbound markers is clearly not anticipated by the references. Withdrawal of the rejections is therefore respectfully submitted.

Rejections under 35 U.S.C. § 103

Claims 16-18 have also been rejected under 35 U.SC. § 103 over *TDK* taken with *Cohen*. As discussed above, these references fail to teach the use of a homogeneous immuno-assay. Thus, it is submitted that this rejection should also be withdrawn.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1, 2, and 3 have been amended to read as follows:

1. (Thrice Amended) A process for qualitative and/or quantitative detection of analytes in a liquid and/or solid phase ~~heterogenous~~ homogeneous immunoassay, comprising determining remanence magnetization in said ~~heterogenous~~ homogeneous immunoassay after addition to a sample of a stable or quasi-stable ferromagnetic or ferrimagnetic substances.

2. (Twice Amended) A process for qualitative and/or quantitative detection of analytes in ~~heterogenous~~ homogeneous immunoassays comprising measuring remanent magnetization of bound magnetic markers in a sample, wherein at the time of measurement the magnetization of unbound magnetic markers that are present in the sample in their totality fades owing to extrinsic superparamagnetism.

3. (Thrice Amended) A process for qualitative and/or quantitative detection of analytes in a liquid or solid phase ~~heterogenous~~ homogeneous immunoassay, comprising

(i) labeling first structure-specific substances, with ferrimagnetic or ferromagnetic substances,

(ii) adding said magnetic labeled structure-specific substances to a sample that is to be measured,

(iii) magnetizing the sample to be measured with the aid of a magnetic field or suitable intensity that is applied from outside and,

(iv) measuring the remanence of the magnetization of bound structure-specific substances with the aid of magnetic field sensors after the external field is shut off~~.~~ without removing unbound structure-specific substances.